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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,489	12/15/2003	Xia Zhao	4133-031323 (P-6125)	3805
32182 7590 07/16/2008 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (The Webb Firm) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07414-1880				
EXAMINER				
CHORBAJI, MONZER R				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
07/16/2008		PAPER		

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte XIA ZHAO,
JANE REN, ROBERT ODELL
and PATTI PATERSON

Appeal 2008-3414
Application 10/736,489
Technology Center 1700

Decided: July 16, 2008

Before BRADLEY R. GARRIS, CATHERINE Q. TIMM, and
MICHAEL P. COLAIANNI, *Administrative Patent Judges*.

GARRIS, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1-6, 8-52, and 54-56. We have jurisdiction under 35 U.S.C. § 6.

We AFFIRM.

Appellants claim a method of sterilizing a prefilled container which comprises the step of irradiating the prefilled container with gamma radiation, wherein the prefilled medium includes less than about 3.4 ppm of oxidizable substances after the irradiating step (claim 17). Appellants also claim a sterilized article comprising a container containing a medium which has been subjected to gamma irradiation sterilization treatment after being filled with the medium, wherein the medium includes less than about 3.4 ppm of oxidizable substances (claim 32).

Representative claims 17 and 32 read as follows:

17. A method of sterilizing a prefilled container comprising:

providing a container made of a composition comprising a polyolefin material and a radiation stabilizer;

filling the container with a medium; and

irradiating said container filled with said medium with gamma radiation, wherein said medium includes less than about 3.4 ppm of oxidizable substances after said irradiating step.

32. A sterilized article comprising:

a container made of a composition comprising a polyolefin material and a radiation stabilizer; and

a medium contained within said container, said medium including less than about 3.4 ppm of oxidizable substances,

wherein said container containing said medium therein has been subjected to a gamma irradiation sterilization treatment after being filled with said medium.

The prior art set forth below is relied upon by the Examiner as evidence of obviousness:

Williams	4,994,552	Feb. 19, 1991
Vellutato	6,123,900	Sep. 26, 2000
Kozimor	6,231,936 B1	May 15, 2001
Saito	6,437,048 B1	Aug. 20, 2002

Jacobs, "The use of gamma-irradiation for the sterilization of water for injections and normal saline solution for injection," *ACTA Pharm. Succ.* 14, 287-292 (1977).

The Admitted Prior Art disclosed at Specification page 2, lines 10-14.

All independent claims 1, 17, 32, and 55 as well as certain dependent claims are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kozimor in view of the Admitted Prior Art. The remaining dependent claims are correspondingly rejected over these references in various combinations with Jacobs, Williams, Saito, and Vellutato.

Independent method claims 1 and 17 have been argued separately from independent article claims 32 and 55 (App. Br. 12-22). None of the dependent claims, including those which have been separately rejected, have been separately argued (*id.*). Accordingly, in assessing the separate arguments advanced by Appellants in this appeal, we select claim 17 to represent the separately argued independent method claims and claim 32 to represent the separately argued independent article claims. See 37 C.F.R. § 41.37(c)(1)(vii).

We will sustain the rejections advanced in this appeal for the reasons expressed in the Answer and below.

There is no dispute that Kozimor teaches alternatively sterilizing containers with gamma irradiation (1) after filling the containers with medium, as recited by the independent claims, or (2) before filling the containers with medium (col. 2, ll. 34-39, col. 4, ll. 10-15, col. 7, ll. 10-16, col. 8, ll. 44-50). According to the Examiner, the gamma sterilization of prefilled containers as taught by Kozimor would inherently produce a prefilled medium which includes less than 3.4 ppm of oxidizable substances after the irradiating step as recited by the independent claims (Ans. 9-10). The Examiner relies on the Admitted Prior Art as evidence that less than about 3.4 ppm of oxidizable substances is a requirement of European and/or US Pharmacopoeia (*id.*).

The Rejection of Method Claim 17

Appellants state that prefilling their container with medium prior to gamma irradiation achieves pharmacologically acceptable properties including less than about 3.4 ppm of oxidizable substances as recited in the independent claims (App. Br. 10-11). Appellants argue that the Applied Prior Art contains no recognition of this stated benefit (App. Br. 14), that Kozimor teaches away from the present invention by disclosing that syringes (i.e., containers) can be filled either before or after irradiation (App. Br. 14-15), and that their discovery (i.e., that filling the container prior to irradiation reduces the level of oxidizable substances) is unexpected (App. Br. 15-16). In addition, Appellants argue that, to establish inherency, the missing descriptive matter must be necessarily present and recognized by persons of ordinary skill in the art (Reply. Br. 2-3) and that the claimed invention

would not necessarily result from following Kozimor and would not be recognized from the Applied Prior Art (Reply Br. 3-4).

As an initial matter, we clarify that a proper prior art rejection based on inherency does not require recognition of the inherent prior art disclosure by a person of ordinary skill in the art. *See Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). This is because inherency is not necessarily coterminous with knowledge of those with ordinary skill in the art and therefore artisans may not recognize the inherent characteristics or functioning of the prior art. *See In re Cruciferous Spout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002).

For this reason, the Examiner's inherency-based rejection is not improper, as Appellants argue, on the ground that an inherent achievement of less than 3.4 ppm of oxidizable substances by Kozimor would not have been recognized.

Appellants are correct that, to establish inherency, the missing descriptive matter must be necessarily present. *See In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). However, there is no persuasive merit in Appellants' argument that the above-noted inherent result would not necessarily occur in following the teachings of Kozimor. This is because patentee's method of sterilizing prefilled containers with gamma radiation is identical to each of the method steps defined by claim 17. Therefore, since the claim 17 method achieves the recited result (i.e., less than about 3.4 ppm of oxidizable substances), the identical method of Kozimor must necessarily and inherently achieve the same result. This rationale establishes a basis in fact and/or technical reasoning in support of an inherency determination. *See Ex parte Levy*, 17 USPQ2d 1461, 1463-64 (BPAI 1990).

Contrary to Appellants' belief, this rationale is not undermined simply because Kozimor also discloses a method of gamma sterilizing containers which have not been prefilled. As correctly observed by the Examiner (Ans. 9), there are only two gamma sterilizing methods taught by Kozimor, namely, to fill then irradiate the container or alternatively to irradiate then fill the container. This limited number of embodiments supports a finding that Kozimor anticipatorily discloses both embodiments including the fill then irradiate embodiment defined by claim 17. Regardless, an artisan certainly would have found it obvious to practice the fill then irradiate embodiment of Kozimor. In any case, Kozimor's alternative embodiment does not discourage and thereby teach away from practicing patentee's fill then irradiate embodiment. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference). As a consequence, there is no convincing merit in Appellants' argument that the alternative method disclosed by Kozimor teaches away from the claim 17 method (which is indistinguishable from patentee's fill then irradiate embodiment).

We also are unpersuaded by Appellants' argument that the claim 17 results (i.e., achieving less than about 3.4 ppm of oxidizable substances) constitute unexpected results (i.e., because they would not have been recognized by artisans following Kozimor's fill then irradiate embodiment). It is irrelevant that artisans following this prior art embodiment may not have appreciated the inherent results under consideration. *See W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

In light of the foregoing, the record of this appeal establishes a prima facie case of unpatentability based on inherency with respect to independent method claim 17. Under these circumstances, it is Appellants' burden to prove that the fill then irradiate embodiment of Kozimor's method does not necessarily or inherently achieve the results required by claim 17. *See, In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). Whether based on anticipation or obviousness, the burden of proof is the same, and its fairness is evidenced by the inability of the Patent and Trademark Office to obtain and compare the claimed and prior art methods. *Id.*

It follows that we sustain the Examiner's § 103 rejection of representative independent method claim 17 as being unpatentable over Kozimor in view of the Admitted Prior Art as well as the § 103 rejections of the other method claims on appeal.

The Rejection of Article Claim 32

Our above discussed rationale for sustaining the rejection of method claim 17 also supports our determination to sustain the rejection of article claim 32.

This determination is further reinforced by the fact that patentability of the claim 32 article is based on the claimed product rather than its process of manufacture. *See In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). As a consequence, the claim 32 article would be satisfied by an identical article resulting from Kozimor's method regardless of whether the container was filled then irradiated (pursuant to one of patentee's embodiments and recited in claim 32) or irradiated then filled (pursuant to patentee's alternative embodiment). Similarly, the claim 32 article would be satisfied by

Kozimor's identical article having less than about 3.4 ppm of oxidizable substances regardless of whether the article was obtained inevitably as the inherent consequence of patentee's fill then irradiate embodiment or was obtained only occasionally (e.g., via patentee's irradiate then fill embodiment) but retained and collected because such an article satisfies the pharmacological requirements of the Admitted Prior Art.

For these reasons, we also sustain the § 103 rejection of representative independent article claim 32 as being unpatentable over Kozimor in view of the Admitted Prior Art as well as the other § 103 rejections of the remaining article claims on appeal.

Conclusion

We have sustained each of the § 103 rejections advanced by the Examiner on this appeal.

The decision of the Examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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DAVID W. HIGHT, VP & CHIEF IP COUNSEL
BECTON, DICKINSON & COMPANY
The WEBB FIRM
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07414-1880